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September 4, 2013

Gary M. Guarino
Assistant United States Attorney
U.S. Department of Justice
District of Alaska
Federal Building & U.S. Courthouse
222 West 7th Avenue, #9, Room 253
Anchorage, AK 99513-7567

RE: **RICHARD J. HELMS**
CASE: Richard J. Helms v. U.S.
CASE NO.: 3:11-cv-00062-TMB
DATE OF BIRTH: October 19, 1959

I was asked to evaluate the medical records regarding the case of Richard J. Helms v. U.S. by Gary M. Guarino, Assistant United States Attorney, U.S. Department of Justice, District of Alaska, Anchorage, AK 99513 in reference to alleged medical malpractice involving failure to administer tPA in a timely manner regarding acute ischemic stroke involving the vascular territory of Mr. Helms' right posterior cerebral artery.

The scope of my assignment in this case is:

1. To establish causation or lack thereof between failure to diagnose Mr. Helms' initial stroke upon presentation at the Nome Hospital Emergency Room at 6:25 a.m. on the morning of August 29, 2008 and any current level of disability
2. To establish whether the failure to administer tPA was the proximate cause of Mr. Helms' stroke
3. To establish the standard of care referenced to Mr. Helms' treatment at the Nome Hospital Emergency Department

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performed on September 2, 2008, in which both the cervical and intracranial vessels disclosed no evidence of occlusion. Continuous heart monitoring will demonstrate episodes of paroxysmal atrial fibrillation, which may last only minutes and revert to normal rhythm (Cotter, P: *Neurology*: 80:1546-1550, 2013; Flint, A: *Neurology* 80:1542-1543, 2013).

- F. tPA may not be administered in the absence of a CT head scan to rule out hemorrhage nor clear evidence of occlusive disease with computerized tomographic angiography (CTA). Neither was available at the Nome Hospital in the summer of 2008.

III. The earlier the stroke victim is treated with IV tPA the better the chance of recovery and blood vessel recanalization.

- A. Treatment within one hour or less of clearly defined onset is associated with the best chance of recovery and the least chance of complication.
- B. tPA is tissue plasminogen activator, a fibrinolytic agent (clot dissolving drug).
- C. Even if Mr. Helms had been timely evaluated and administered tPA, there is no way to predict in any individual case the recanalization rate of blocked arteries or improvement in a patient's stroke condition.
- D. Medical literature memorializes only a 50 percent recanalization rate occurring in patients who are administered IV tPA, and the treatment results in an absolute increase in the odds of a good outcome of 11 to 13 percentage points with a 6 percent risk of intracerebral hemorrhage possibly causing worsening or death.
- E. To a reasonable degree of medical probability, success cannot be predicted in any given patient. A successful outcome occurs in approximately 11 to 13 percent of patients and in some of these patients only a partial or suboptimal recovery occurs. Even under the best of circumstances, only a small percent of patients are helped by administration of this drug.

IV. Given the benefit ratio of stroke amelioration in only 11 to 13 percent of stroke victims, no predication can be made in any individual case of stroke resolution. Multiple stroke risk factors, including morbid obesity, are associated with poorer outcomes and higher complication rates, including intracerebral hemorrhage.

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VIII. Mr. Helms is at high risk for future stroke given the multiplicity of his risk factors.

IX. Mr. Helms requires outpatient continuous cardiac monitoring to elucidate the incidence of paroxysmal atrial fibrillation.

My opinions were formulated based on the information I had at the time this analysis was dictated. If additional medical records or information are submitted to me as further discovery progresses, I reserve the right to amend, alter or expand any opinions reached in this case.

Sincerely,



Richard A. Rubenstein, M.D.

RAR:jc

Enc.

Exhibit D